

MSAC Application 1771.1

**Axicabtagene ciloleucel therapy for
patients with relapsed or refractory
follicular lymphoma**

Application for MBS eligible service or health technology

HPP Application number:

HPP200262

Application title:

Resubmission Axicabtagene ciloleucel for patients with relapsed/refractory follicular lymphoma

Submitting organisation:

GILEAD SCIENCES PTY LIMITED

Submitting organisation ABN:

71072611708

Application description

Succinct description of the medical condition/s:

Follicular Lymphoma (FL) is a type of blood cancer that changes certain blood cells in your body called B-cell lymphocytes (B-cells). It can affect your lymph nodes (sometimes called glands) and your lymphatic system. These are all part of your body's immune system which fight infection and disease. Follicular lymphoma is considered an indolent lymphoma, which means it is usually slow growing and often "sleeping", so many people with FL do not need active treatment during indolent stages of their disease. However, if your FL "wakes up" and starts to grow, you may experience symptoms and need treatment.

Source Lymphoma Australia: <https://www.lymphoma.org.au/types-of-lymphoma/non-hodgkin-lymphoma/indolent-slow-growing-b-cell-nhl/follicular-lymphoma/> [accessed 22 Oct 2023]

Succinct description of the service or health technology:

Axicabtagene ciloleucel is a CAR T-cell therapy that is produced using a patient's own T-cells (another form of immune cell), making the product unique to each patient. For CAR-T therapy, a patient's T-cells are collected and genetically modified in a lab to express an anti-CD19 chimeric antigen receptor (CAR) that targets the lymphoma B-cells. The modified T-cells are multiplied and then infused back into the patient where they target and kill the cancerous lymphoma B-cells, thereby treating the

lymphoma.

Axicabtagene ciloleucel is used when patients with follicular lymphoma do not respond to (refractory), or relapse (come back) after, other types of treatment, such as chemotherapy.

Application contact details

Are you applying on behalf of an organisation, or as an individual?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

Applicant organisation name:

GILEAD SCIENCES PTY LIMITED

Application details

Please select the program through which the health technology would be funded:

National Health Reform Agreement Addendum (Highly specialised therapies)

Please provide justification for selecting the above program:

The application seeks joint funding by the Commonwealth and states and territories through the High Cost, Highly Specialised Therapy arrangements included in the National Health Reform Agreement (NHRA) Addendum 2020–25.

This program is the current funding mechanism for CAR T-cell therapies provided in Australia.

Is the application for a new listing or a change to an existing listing?

New listing

What is the type of service or health technology?

Therapeutic

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type
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What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO set:

PICO set name
Axicabtagene ciloleucel for patient with relapsed/refractory follicular lymphoma

Population

Describe the population in which the proposed health technology is intended to be used:

Adult patients with Grade 1, Grade 2 or Grade 3a follicular lymphoma and relapsed or refractory disease after two or more lines of therapy.

Select the most applicable Medical condition terminology (SNOMED CT):

Follicular non-Hodgkin's lymphoma

Intervention

Name of the proposed health technology:

Yescarta™ (axicabtagene ciloleucel)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Standard of Care (SoC), represented by a 'basket' of anti CD20 monotherapy, anti CD20 therapy in combination with chemotherapy and chemotherapy regimens.

Standard of Care requires administration by intravenous infusion. This would take place in outpatient clinics and is funded through MBS item 13950.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Not applicable. Yescarta is not a test used for diagnostic or risk assessment purposes.

Specified restrictions for funding

Please add one or more items, with specified restriction for funding, for each Population / Intervention:

Proposed item:

AAAAA

Is the proposed item restricted:

Yes – restricted

Provide a short description of the restriction:

Patients who have relapsed/refractory follicular lymphoma who have failed at least 2 lines of therapy

Proposed price of supply:

Redacted

Indicate the overall cost per patient of providing the proposed health technology:

Redacted

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Yescarta is not currently funded for the treatment of patients with relapsed or refractory follicular lymphoma.

Yescarta is currently funded for the treatment of adults relapsed or refractory large B-cell lymphoma through the National Health Reform Agreement Addendum (Highly Specialised Therapies).

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Superior

Please state what the overall claim is, and provide a rationale:

Claim is based on the indirect comparison between ZUMA-5 study and the external cohort SCHOLAR-5 study. Additional data for ZUMA-5 is now available with a data cut-off of 60 months.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

In 2023 it was estimated that less than 200 adult patients with Grade 1, Grade 2 or Grade 3a follicular lymphoma that commenced second line therapy within 24 months of diagnosis. This patient cohort would become eligible for Yescarta upon developing relapsed or refractory disease after their second line therapy.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

to be provided

Year 2 estimated uptake (%):

to be provided

Year 3 estimated uptake (%):

to be provided

Year 4 estimated uptake (%):

to be provided

Estimate the number of patients who will utilise the proposed technology for the first full year:

Less than 200

Optionally, provide details:

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service

Australia and New Zealand Transplant and Cellular Therapies society (ANZTCT)

Haematology Society of Australia and New Zealand (HSANZ)

The Australian Leukaemia and Lymphoma Group (ALLG)

Entity who may be impacted by the health technology/service

Novartis Australia and New Zealand

Entity who produces similar products

Australia and New Zealand Transplant and Cellular Therapies society (ANZTCT)

Haematology Society of Australia and New Zealand (HSANZ)

The Australian Leukaemia and Lymphoma Group (ALLG)

Patient and consumer advocacy organisations relevant to the proposed service/health technology

Lymphoma Australia

Rare Cancers Australia

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? *(if 'Yes' above)*

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
400895	Cellular Therapies - T Cells - Axicabtagene ciloleucel, cryopreserved - T - Yescarta - Gilead Sciences Pty Ltd - Injection, intravenous infusion - Bag

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No